

FORM PTO-1390 (Modified)
(REV 11-2000)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

217994US3PCT

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR

10/019295

INTERNATIONAL APPLICATION NO.

PCT/GB00/02588

INTERNATIONAL FILING DATE

5 July 2000

PRIORITY DATE CLAIMED

5 July 1999

TITLE OF INVENTION

METHOD AND APPARATUS FOR FOCUSSING ULTRASONIC ENERGY

APPLICANT(S) FOR DO/EO/US

YOUNG Michael et al.


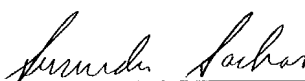
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☒ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. ☐ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made, however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☒ A copy of the International Search Report (PCT/ISA/210).

Items 13 to 20 below concern document(s) or information included:

13. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☐ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
20. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
22. ☐ Certificate of Mailing by Express Mail
23. ☒ Other items or information:

Notice of Priority/Form PTO-1449

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 10/019295)		INTERNATIONAL APPLICATION NO. PCT/GB00/02588		ATTORNEY'S DOCKET NUMBER 217994US3PCT	
24. The following fees are submitted: BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) : <input type="checkbox"/> Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO \$1040.00 <input checked="" type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO \$890.00 <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$740.00 <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$710.00 <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) \$100.00 ENTER APPROPRIATE BASIC FEE AMOUNT =				CALCULATIONS PTO USE ONLY	
Surcharge of \$130.00 for furnishing the oath or declaration later than _____ months from the earliest claimed priority date (37 CFR 1.492 (e)). <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30				\$890.00	
				\$130.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	- 20 =	0	x \$18.00	\$0.00	
Independent claims	- 3 =	0	x \$84.00	\$0.00	
Multiple Dependent Claims (check if applicable).			<input type="checkbox"/>	\$0.00	
TOTAL OF ABOVE CALCULATIONS =				\$1,020.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27). The fees indicated above are reduced by 1/2.				\$0.00	
SUBTOTAL =				\$1,020.00	
Processing fee of \$130.00 for furnishing the English translation later than _____ months from the earliest claimed priority date (37 CFR 1.492 (f)). <input type="checkbox"/> 20 <input type="checkbox"/> 30 +				\$0.00	
TOTAL NATIONAL FEE =				\$1,020.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable).			<input type="checkbox"/>	\$0.00	
TOTAL FEES ENCLOSED =				\$1,020.00	
				Amount to be refunded	\$
				charged	\$
a. <input checked="" type="checkbox"/> A check in the amount of <u>\$1,020.00</u> to cover the above fees is enclosed.					
b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of _____ to cover the above fees. A duplicate copy of this sheet is enclosed.					
c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>15-0030</u> . A duplicate copy of this sheet is enclosed.					
d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.					
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.					
SEND ALL CORRESPONDENCE TO: <u>Surinder Sachar</u>					
Registration No. 34,423					
 22850					
 SIGNATURE					
C. Irvin McClelland NAME					
21,124 REGISTRATION NUMBER					
<u>Jan. 4 2002</u> DATE					

217994US-3-PCT

Rec'd PGT/PTO 22 MAR 2002

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :
MICHAEL YOUNG ET AL : ATTN: APPLICATION DIVISION
SERIAL NO: 10/019,295 :
FILED: JANUARY 4, 2002 :
FOR: METHOD AND APPARATUS FOR:
FOCUSSING ULTRASONIC ENERGY

PRELIMINARY AMENDMENT

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

Prior to a first examination on the merits, please amend the above-identified application as follows:

IN THE CLAIMS

Please cancel Claims 1-12 without prejudice.

Please add new Claims 13-23 as follows:

13. (New) An apparatus for treatment of subcutaneous tissue comprising:
means for generating ultrasonic vibrations;
a substantially plano-concave lens disposed immediately adjacent the means for
generating ultrasonic vibrations to focus the ultrasonic vibrations at a focal point within the
tissue; and
means for moving the focal point.

14. (New) An apparatus as claimed in claim 13, wherein the means for moving the focal point comprises means for mounting the lens to be longitudinally movable so that an effective location of the focal point is movable to impinge directly on the tissue to be treated.

15. (New) An apparatus as claimed in claim 14, wherein the means for mounting the lens is movable with respect to a surface of a body above the tissue to be treated.

16. (New) An apparatus as claimed in claim 13, wherein the means for generating ultrasonic vibrations includes a plurality of generator means for generating ultrasonic vibrations, each of said plurality of generator means provided with a respective substantially plano-concave lens to focus the ultrasonic vibration at said focal point within the tissue.

17. (New) An apparatus as claimed in claim 13, wherein the lens comprises a material selected from the group consisting of: titanium, an alloy of titanium, aluminum, and an alloy of aluminum.

18. (New) An apparatus for treatment of subcutaneous tissue comprising:
at least one ultrasonic generator configured to generate ultrasonic vibrations;
at least one substantially plano-concave lens disposed immediately adjacent the at least one ultrasonic generator to focus the ultrasonic vibrations at a focal point within the tissue; and

a mounting mechanism configured to mount the lens to be moveable to move the focal point.

19. (New) An apparatus as claimed in claim 18, wherein the lens is movable with respect to a surface of a body above the tissue to be treated.

20. (New) An apparatus as claimed in claim 18, wherein the at least one ultrasonic generator includes a plurality of ultrasonic generators, each of said plurality of ultrasonic generators provided with a respective substantially plano-concave lens to focus the ultrasonic vibration at said focal point within the tissue.

21. (New) An apparatus as claimed in claim 18, wherein the lens comprises a material selected from the group consisting of: titanium, an alloy of titanium, aluminum, and an alloy of aluminum.

22. (New) A method of treatment of subcutaneous tissue utilizing an apparatus including at least one ultrasonic generator configured to generate ultrasonic vibrations, at least one substantially plano-concave lens disposed immediately adjacent the at least one ultrasonic generator to focus the ultrasonic vibrations at a focal point within the tissue, and a mounting mechanism configured to mount the lens to be moveable to move the focal point, the method comprising:

applying said apparatus to a body within which lies the tissue to be treated; and

moving the at least one ultrasonic generator and the mounting mechanism so that their effective distance from a body surface above the tissue to be treated is such that the focal point of the lens is coincident with the tissue to be treated.

23. (New) A method as claimed in claim 22, wherein the target tissue comprises blood vessels.

IN THE ABSTRACT

Please amend the Abstract on page 10 to read as follows:¹

ABSTRACT

An apparatus for treatment of subcutaneous tissue including ultrasonic, e.g. piezoelectric, generators to generate ultrasonic vibrations. Each generator has a lens to focus the ultrasonic vibration at a point within the tissue. The focal point may be moved so that the generated ultrasonic vibrations may be focussed exactly at a point within the tissue that

¹A marked-up copy of the amendments is attached hereto.

requires treatment. The energy enters the surface of the body over a very wide area, and therefore causes minimum damage to healthy overlying tissue.

REMARKS

Favorable consideration of this application, as presently amended, is respectfully requested.

The present Preliminary Amendment is submitted to place the above-identified application in more proper format under United States practice.

By the present Preliminary Amendment original Claims 1-12 are cancelled and new Claims 13-23 are presented for examination. New Claims 13-23 are believed to be self-evident from the original disclosure, and thus are not deemed to raise any issues of new matter.

The Abstract has also been amended by the present response to be in more proper format under United States practice.

The present application is believed to be in condition for a full and thorough examination on the merits. An early and favorable consideration of the present application is hereby respectfully requested.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



Gregory J. Maier
Attorney of Record
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217994US-3-PCT

Marked-Up Copy

Serial No: 10/019,295

Amendment Filed on:

IN THE CLAIMS

Claims 1-12 (Cancelled).

Claims 13-23 (New).

IN THE ABSTRACT

Please amend the Abstract on page 10 to read as follows:

--ABSTRACT

[METHOD AND APPARATUS FOR FOCUSSED
ULTRASONIC ENERGY]

An apparatus for treatment of subcutaneous tissue [comprising] including piezoelectric generators [(1)] to generate ultrasonic vibrations. Each generator has a lens [(2)] to focus the ultrasonic vibration at a point [(3)] within the tissue. The focal point may be moved so that the generated ultrasonic vibrations may be focussed exactly at a point within the tissue [which] ~~that~~ requires treatment. The energy enters the surface of the body over a very wide area, and therefore causes minimum damage to healthy overlying tissue.--

JG13 Rec'd PCT/PTO 04 JAN 2002

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METHOD AND APPARATUS FOR FOCUSSED ULTRASONIC ENERGY

The present invention relates to a method and apparatus for focussing ultrasonic energy. More particularly, but not exclusively, it relates to an apparatus and method for treatment of subcutaneous tissue utilising non-invasive focussed ultrasound.

Tissue which may be treated by the method and apparatus includes subcutaneous blood vessels, unsightly thread veins, selected cancer tissue, and the like. The apparatus may be used for haemostatic cutting and cauterising of blood vessels. It may also be used in other, non-medical, areas where it is desired to apply high intensity energy to a small target zone.

One tissue type which may benefit from such treatment comprises fine arteries and veins lying closely beneath the dermis

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It is well known that fine arteries and veins may become visible in quite random areas closely beneath the dermis. Where these are visible through the dermis in a localised area, these arteries or veins may constitute a serious visual skin blemish.

It is known to remove or treat such blood vessels either using laser energy or by forms of invasive surgery so that the blood supply to that particular part of the vascular system is permanently interrupted and the unsightly blemish may be removed.

However, such known methods of treatment may cause collateral damage to the tissue of the patient being treated or may require lengthy recovery periods.

Similarly, it is well known that certain types of cancerous cell may lie close beneath the surface, such as melanomas or even prostate cancers. Such cancers can sometimes be treated by means of laser irradiation, but there may be damage to surrounding tissue and to the outer layers of the dermis and this may be unacceptable.

It is an object of the present invention to provide a method and apparatus for treatment of subcutaneous tissue which obviates the above disadvantages.

According to a first aspect of the present invention, there is provided an apparatus for treatment of subcutaneous tissue comprising means to generate ultrasonic vibrations, means to focus said ultrasonic vibration at a point within said tissue, and means to move said focal point.

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The apparatus may comprise a plurality of generator means to generate ultrasonic vibrations, each being provided with means to focus said ultrasonic vibration at said point within the tissue.

Preferably said means to focus said ultrasonic vibration at said point within tissue comprises lens means.

In the case where there are a plurality of generating means, each may be provided with a respective lens.

The or each lens may be plano-concave.

The or each lens may comprise titanium, titanium alloy, aluminium or an alloy thereof.

The or each lens may be disposed immediately adjacent the respective generator means.

The lens means may be so mounted that the location of the focal point thereof may be moved to impinge directly on the tissue to be treated.

Means to hold the lens means may be movable with respect to the body within which lies the tissue to be treated.

According to a second aspect of the present invention, there is provided a method of treatment of subcutaneous tissue comprising the steps of providing an apparatus as described above, applying said apparatus to a body within which lies the tissue to be treated, and

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moving said ultrasonic generation means and said focussing means so that their effective distance from to the body within which lies the tissue to be treated is such that the focal point of the lens is coincident with the tissue to be treated.

The tissue to be treated may be subcutaneous blood vessels.

Embodiments of the present invention will now be more particularly described by way of example and with reference to the accompanying drawings, in which:-

Figure 1 shows schematically a system for generating high intensity focused ultrasound;

Figure 2 is a cross-sectional view of an apparatus utilising high intensity focused ultrasound for targeting on to a selected blood vessel;

Figure 3 is a cross-sectional view of an apparatus including three ultrasonic generators; and

Figure 4 is a plan view of the apparatus of Figure 3.

Referring now to Figure 1 and 2 of the drawings, a piezoelectric ceramic disc 1 is adapted to produce high frequency ultrasound in the 1-5 MHz range when excited at an appropriate frequency by electrical means (not shown). Immediately adjacent to the piezoelectric ceramic disc 1 is a focusing plano-concave lens 2 of aluminium alloy or titanium alloy or other suitable material, whereby the ultrasonic vibration is directed to a focal point 3 within the body wherein is located tissue, in this case a blood vessel 4, to be treated.

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The focal point 3 may require to be moved to take account of the depth of the blood vessel 4 within the tissue, so that the focal point 3 of the ultrasonic vibration coincides with the vessel 4. This is achieved by moving the assembled piezoelectric disc 1 and lens 2 either towards or away from the surface of the tissue.

Movement is determined according to the formula:

$$f = h + t$$

where f is the focal length of lens 2;

t is the depth of the target tissue 4 beneath the body surface; and

h is the height of the lens 2 above the body surface.

Since f is a predetermined constant, for any variation in t , h must be changed.

The assembly of piezoelectric disc 1 and lens 2 is mounted to an inner holder 5 which is itself held to be longitudinally movable with respect to an outer holder 6. A container 7 surrounds the outer holder 6 and is provided with a seal 8 to engage sealingly the body surface. The container 7 is adapted to hold a coupling fluid medium 9, at least filling that part of its volume separating the lens 2 from the body surface. The medium 9 is preferably a gelatinous or aqueous liquid capable of transmitting the ultrasonic vibrations between transmitting head assembly 1 and 2 and the body surface. A second seal 10 is provided between the relatively movable inner holder 5 and outer holder 6.

As may be seen, use of the invention enables direct absorption of substantially all generated ultrasonic vibrations at a target point within the tissue. This direct absorption of ultrasound in the 1 – 5 MHz range will cause the temperature of the relatively small volume of the target

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tissue to rise rapidly, which will cause local coagulation of the vessel 4. Such treatment, when applied over an area of a visual skin blemish, should remove the offending blemishing vessels and improve the appearance of the area.

A further, more powerful, embodiment of the apparatus is shown in Figures 3 and 4. In this case, there are provided three ultrasonic generators 1, each associated with a respective plano-concave lens 2. Each of the three generator assemblies is attached by means of a bonding material 12 to a curved mounting plate 11. This mounting plate 11 forms one side of a liquid filled chamber 15, the other side of which is formed by a membrane 14 adapted to contact the surface of the body overlying the target tissue. The membrane 14 is sufficiently flexible to adapt itself to the shape of the body surface and the membrane material has good transmission for ultrasonic vibrations at the frequency (1 ~ 5 MHz) being used.

The apparatus including the three generator heads 1 is supported within a container 16 which enables the apparatus to be moved over the surface above the tissue to be treated.

As may be seen, each of the three generators 1 may individually be of comparatively low power intensity, but since all three are focused on the same point 3 within the tissue, the energy at that point 3 is markedly intensified- three times that of the intensity of any one of the individual already focussed beams. As is clear from the Figures, the intensity of the ultrasound at the surface of the body is very low, with any adverse effects minimised because of the wide area within which the beams enter the body. The intensity increases only gradually through the layers of dermis and epidermis to an intensely focus at point 3.

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If so desired, more than three generator heads may be used, for example five in a cross configuration, seven in a circular configuration, or any number in any desired arrangement.

The use of the invention has been described by way of a method and apparatus to treat subcutaneous tissue, whether it is blood vessels or cancerous tissue. However, many other uses for the apparatus may be found, and it is not limited to a medical use.

CLAIMS

1. An apparatus for treatment of subcutaneous tissue comprising means to generate ultrasonic vibrations, means to focus said ultrasonic vibration at a point within said tissue, and means to move said focal point.
2. An apparatus as claimed in claim 1, wherein there is provided a plurality of generator means to generate ultrasonic vibrations, said plurality of generator means being provided with means to focus said ultrasonic vibration at said point within the tissue.
3. An apparatus as claimed in either claim 1 or claim 2, wherein said means to focus said ultrasonic vibration at a point within the tissue comprises lens means.
4. An apparatus as claimed in claim 2, wherein said plurality of generator means is provided with lens means to focus said ultrasonic vibrations at a single point within the tissue.
5. An apparatus as claimed in claim 4, wherein each of said plurality of generator means is provided with a respective lens means.
6. An apparatus as claimed in any one of claims 3 to 5, wherein the or each lens means is substantially plano-concave.
7. An apparatus as claimed in any one of claims 3 to 6, wherein the or each lens comprises titanium, an alloy thereof, aluminium or an alloy thereof.

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8. An apparatus as claimed in any one of claims 3 to 7, wherein the or each lens means is disposed immediately adjacent the or a respective generator means.
9. An apparatus as claimed in any one of claims 3 to 8, wherein the or each lens means is so mounted that the effective location of the focal point thereof is movable to impinge directly on the tissue to be treated.
10. An apparatus as claimed in claim 9, wherein means to hold the lens means are movable with respect to the surface of the body above the tissue to be treated.
11. A method of treatment of subcutaneous tissue comprising the steps of providing an apparatus as claimed in any one of the preceding claims, applying said apparatus to a body within which lies the tissue to be treated, and moving said ultrasonic generation means and said focussing means so that their effective distance from the body surface above the tissue to be treated is such that the focal point of the lens is coincident with the tissue to be treated
12. A method as claimed in claim 11, wherein the target tissue comprises blood vessels.

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ABSTRACT**METHOD AND APPARATUS FOR FOCUSING
ULTRASONIC ENERGY**

An apparatus for treatment of subcutaneous tissue comprising piezo electric generators (1) to generate ultrasonic vibrations. Each has a lens (2) to focus the ultrasonic vibration at a point (3) within the tissue. The focal point may be moved so that the generated ultrasonic vibrations may be focussed exactly at a point within the tissue which requires treatment. The energy enters the surface of the body over a very wide area, and therefore causes minimum damage to healthy overlying tissue.

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DOCKET # 217994US3R SHEET 1 OF 3

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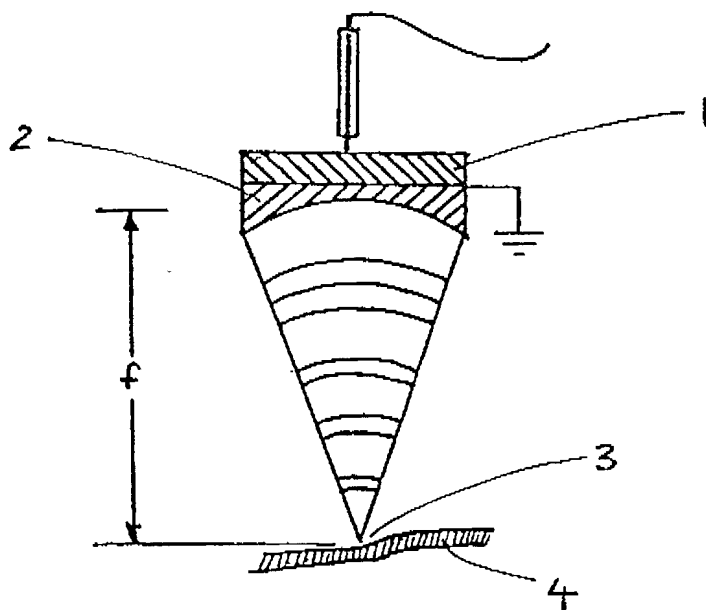


Fig 1

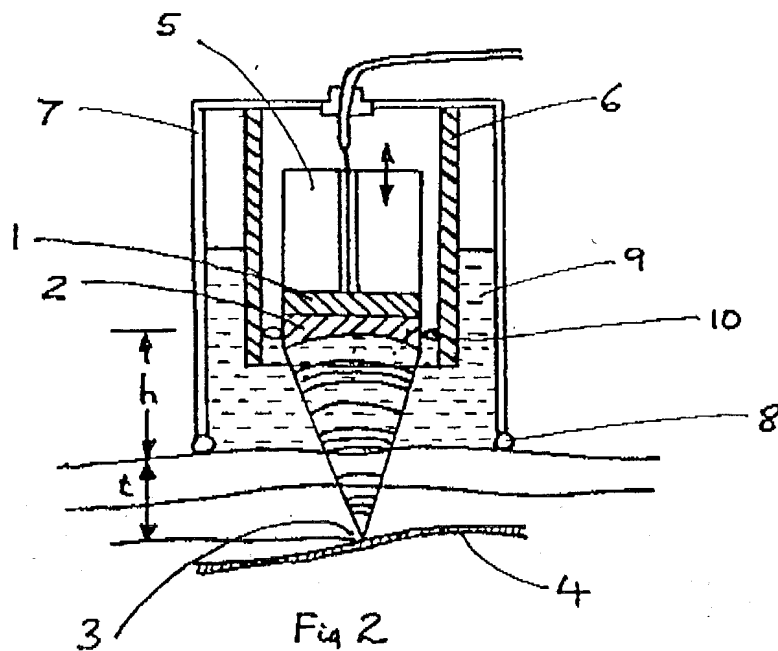


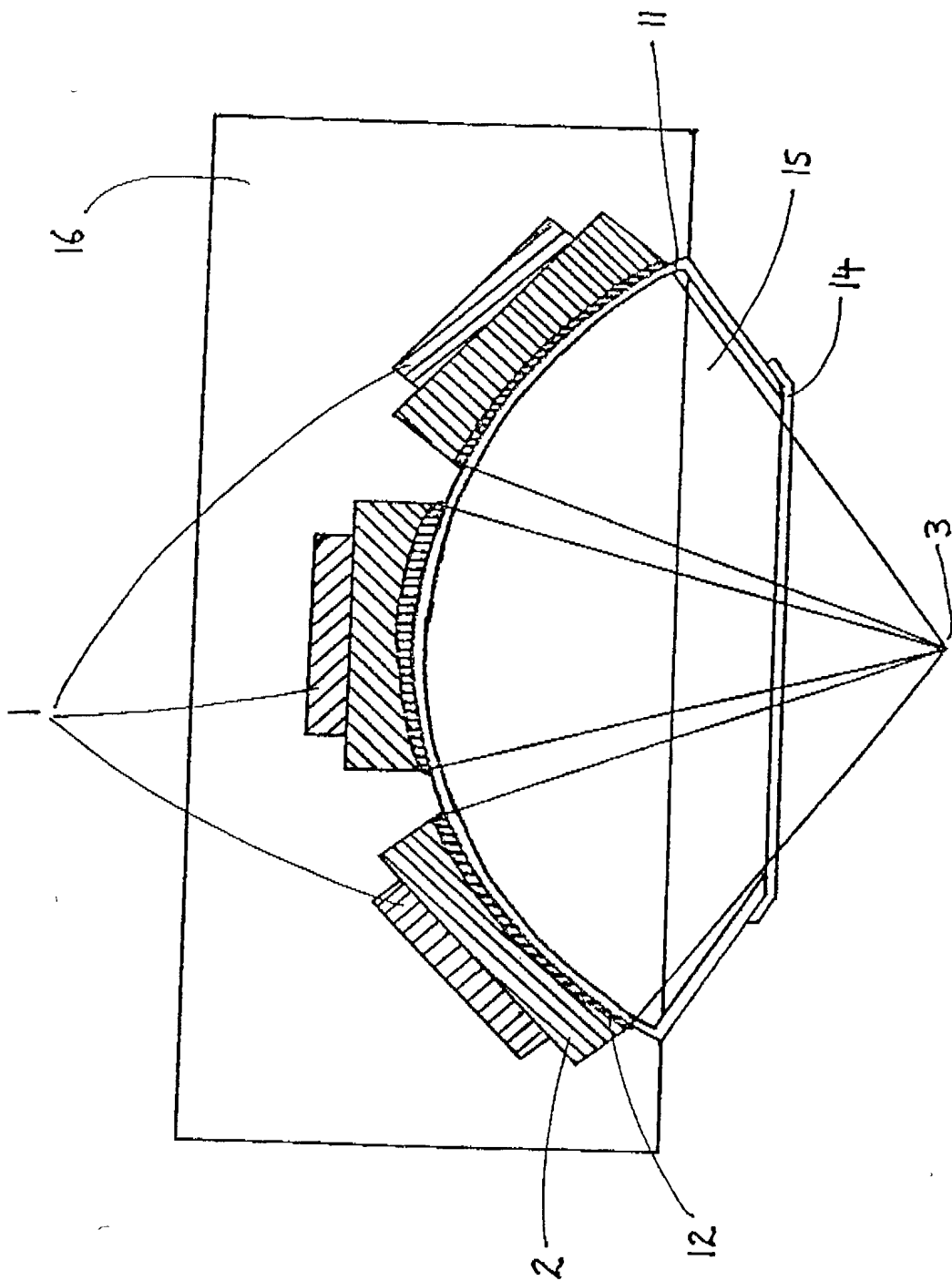
Fig 2

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Fig 3



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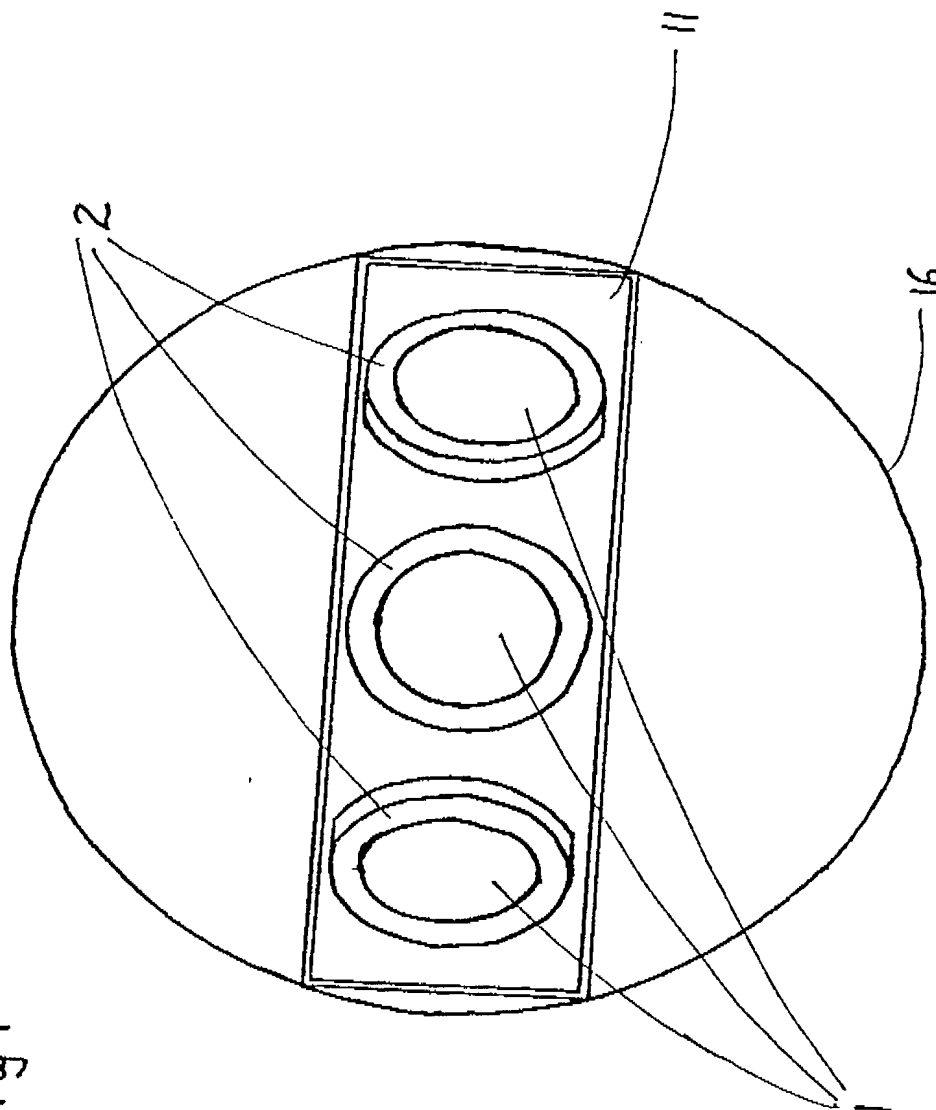


Fig 4

217994US3PCT

Declaration, Power of Attorney and Petition

Page 1 of 3

WE (I) the undersigned inventor(s), hereby declare(s) that:

My residence, post office address and citizenship are as stated below next to my name,

We (I) believe that we are (I am) the original, first and joint (sole) inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled

METHOD AND APPARATUS FOR FOCUSSED ULTRASONIC ENERGY

the specification of which

- ☐ is attached hereto.
- ☒ was filed on January 4, 2002 as
Application Serial No. 10/019,295
and amended on _____
- ☒ was filed as PCT international application
Number PCT/GB00/02588
on July 5, 2000,
and was amended under PCT Article 19
on _____ (if applicable).

We (I) hereby state that we (I) have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

We (I) acknowledge the duty to disclose information known to be material to the patentability of this application as defined in Section 1.56 of Title 37 Code of Federal Regulations.

We (I) hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or PCT International application having a filing date before that of the application on which priority is claimed. Prior Foreign Application(s)

Application No.	Country	Day/Month/Year	Priority Claimed	
9915707.5	Great Britain	5 July 1999	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No
			<input type="checkbox"/> Yes	<input type="checkbox"/> No
			<input type="checkbox"/> Yes	<input type="checkbox"/> No
			<input type="checkbox"/> Yes	<input type="checkbox"/> No

10/01

We (I) hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below.

_____ (Application Number)	_____ (Filing Date)
_____ (Application Number)	_____ (Filing Date)

We (I) hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or under § 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR § 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application.

Application Serial No.	Filing Date	Status (pending, patented, abandoned)
_____	_____	_____
_____	_____	_____
_____	_____	_____

And we (I) hereby appoint the following registered practitioner(s):



as our (my) attorneys, with full powers of substitution and revocation, to prosecute this application and to transact all business in the Patent Office connected therewith; and we (I) hereby request that all correspondence regarding this application be sent to



We (I) declare that all statements made herein of our (my) own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

120 Michael John Radley YOUNG
NAME OF FIRST SOLE INVENTOR

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South Devon TQ13 7JX, Great Britain *CBK*


Michael John Radley
Signature of Inventor

Citizen of: Great Britain

Mailing Address: same as above

✓ 29/01/02
Date

200 Stephen Michael Radley YOUNG
NAME OF SECOND JOINT INVENTOR


Signature of Inventor

29/1/02
Date

NAME OF THIRD JOINT INVENTOR

Signature of Inventor

Date

NAME OF FOURTH JOINT INVENTOR

Signature of Inventor

Date

NAME OF FIFTH JOINT INVENTOR

Signature of Inventor

Date

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Citizen of: Great Britain

Mailing Address: same as above

Residence:

Citizen of:

Mailing Address:

Residence:

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Residence:

Citizen of:

Mailing Address: